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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/697,079 10/27/00 FOX

D 0942,4460002

| EXAMINER |
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HM12/0919

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C
ATTORNEYS AT LAW
SUITE 600
1100 NEW YORK AVENUE, N.W.
WASHINGTON DC 20005-2540

| ART UNIT | PAPER NUMBER |
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1655

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DATE MAILED:

09/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/697,079

Applicant(s)

Fox et al

Examiner

Diana Johannsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 18, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-49 and 52 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-49 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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FINAL ACTION

1. This action is in response to paper no. 5 filed July 18, 2001. Claims 45 and 47 have been amended and claims 37-43, 50 and 51 have been canceled. Claims 45-49 and 52 are now pending. The amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims. **This action is FINAL.**
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 U.S.C. § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY
APPLICANTS AMENDMENTS TO THE CLAIMS:**

4. Claims 45-49 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 45-49 and 52 are indefinite over the recitation of the limitation "wherein said composition does not comprise a nucleic acid molecule" in claim 45. It is unclear as to how this

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recitation is intended to limit the claims. Particularly, it is unclear as to whether applicants intent is to require a composition in which all types of nucleic acids are absent, whether applicants intent is for the claims to encompass any composition in which any particular "nucleic acid molecule" is absent, etc. Accordingly, the metes and bounds of the claims cannot be determined.

Claim Rejections - 35 U.S.C. § 102

5. In view of the cancellation of claims 37-42 and 50-51, the rejection of these claims under 35 U.S.C. 102(e) as being clearly anticipated by Chenchik et al (U.S. Patent No. 5,565,340 [10/15/1996; filed 1/27/1995]) is moot.

6. Claims 45-49 and 52 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Chenchik et al (U.S. Patent No. 5,565,340 [10/15/1996; filed 1/27/1995]).

The response traverses the rejection on the following grounds. The response argues that the present claims "are drawn to compositions comprising one or more restriction endonucleases and one or more polymerase inhibitors, which do not comprise nucleic acid molecules," and that "Chenchik does not disclose such compositions". The response states that "all of the compositions disclosed by Chenchik contain nucleic acid molecules (specifically, PCR products)", and that "Chenchik therefore fails to expressly or inherently disclose every element of the invention as it is now claimed".

These arguments have been thoroughly considered but are not convincing for the following reasons. First, it is noted that present claims are not limited to compositions in which

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“nucleic acid molecules” or any types of nucleic acids are absent. Rather, the claims require that “said composition does not comprise a nucleic acid molecule”. While Chenchik does disclose some compositions comprising nucleic acid molecules (e.g., PCR products), most nucleic acid molecules known in the art are in fact absent from those compositions. Accordingly, even the compositions of Chenchik that contain some types of nucleic acids meet the limitation of not comprising “a nucleic acid molecule”. Second, it is noted that Chenchik et al also inherently disclose compositions comprising a restriction endonuclease and a polymerase inhibitor in which nucleic acids are absent. Applicant is again referred to the Example at col 20, lines 38-67, col 21, lines 1-32. In particular, at lines 26-28, Chenchik et al disclose that PCR products “were examined on a 1.2% agarose/ethidium bromide (EtBr) gel”. It is well known to those of ordinary skill in the art that such a display of digested PCR products results in migration of the nucleic acids present in a liquid amplification product sample into semisolid, gel material. As a result of this migration of nucleic acids from liquid into gel, the remaining liquid composition lacks the presence of nucleic acids. Accordingly, Chenchik et al inherently disclose a liquid composition lacking the presence of nucleic acids, which liquid composition also meets the limitations of the present claims.

As Chenchik et al teach all the limitations recited in present claims 45-49 and 52, therefore this rejection is maintained.

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7. In view of the cancellation of claims 37-42, the rejection of these claims under 35 U.S.C. 102(e) as being clearly anticipated by Scalice et al (U.S. Patent No. 5,587,287 [12/24/1996; filed 4/7/1994]) is moot.

Claim Rejections - 35 U.S.C. § 103

8. In view of the cancellation of claims 42-43, the rejection of these claims under 35 U.S.C. 103(a) as being unpatentable over Chenchik et al (U.S. Patent No. 5,565,340 [10/15/1996; filed 1/27/1995]) in view of Ahern (The Scientist 9(15):20 [7/1995]) and the Stratagene Cloning Systems catalog (Stratagene, 1994, p. 90) is moot.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday from 7:00 a.m. to 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at 703/308-1152. The fax phone number for the Technology Center where this application or proceeding is assigned is 703/305-3014 or 305-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana Johannsen

September 17, 2001


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

9/17/01